IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION OF:	
WHITSON, Debi	Group Art Unit No.: 3626
Serial No.: 09/802,546	Docket No. 36357
Filed: March 9, 2001	Examiner: PORTER, Rachel L.
PROCESS OF INTERFACING A PATIENT INDIRECTLY WITH THEIR OWN ELECTRONIC MEDICAL RECORDS	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDED DECLARATION OF RHETAH KWAN UNDER 37 C.F.R. § 1.132

1. I, Rhetah Kwan, of 3535 SW Multnomah Blvd., Number 146, Portland, Oregon, am making this declaration in support of the above-referenced patent application (the "Application"). I am not an inventor of the invention described in the Application, and I do not have any ownership interest in the Application. Furthermore, I have never been employed by Debi Whitson or otherwise entered into a business relationship of any kind with Ms. Whitson.

2. From 1990 until 2002 I was employed by MedicaLogic, Inc., a company specializing in the development, deployment, and support of software and hardware used by doctors' offices and other caregivers to manage electronic medical records ("EMR"). While employed at MedicaLogic, my responsibilities included assisting customers with installing and implementing EMR software and hardware, as well as providing training and consulting services regarding EMRs. Thus, as a consequence of my job duties while

employed with MedicaLogic for approximately twelve years, I learned the details of the EMR software from the engineers who developed it, including how the EMR software worked, features of the software, and other third-party products, if any, that worked in conjunction with the EMR software. I then presented this knowledge to our customers. By the time I left MedicaLogic in 2002, the company had grown to a nationally-recognized provider of EMR software.

3. During my approximately twelve years with MedicaLogic, I also became very familiar with competing EMR products and was knowledgeable regarding the competing EMR software on the market, what the competing EMR software provided, and how the competing EMR software operated.

4. Since my departure from MedicaLogic in 2002, I have not been directly involved in the EMR software industry.

5. As an individual with many years of experience in the EMR industry, I have been asked to provide this declaration to attest to the state of the art prior to and following the filing date of the Application.

6. EMRs allow a caregiver, such as a doctor's office, to maintain a patient's medical history, environment, symptoms, and other pertinent information, in an electronic format. Caregivers like this ability because they no longer need to maintain paper hard copies of the patient's file. Additionally, if patient information is entered immediately and prior to a doctor or nurse seeing the patient, then the doctor or nurse can obtain the patient's information via use of a computer or hand-held computing device during the doctor's or nurse's visit with the patient.

7. However, the problem arises that it is difficult to input patient information into the EMR in a timely manner so that the doctor or nurse can access the information during the patient's visit to the caregiver's office. Thus, manual submission of patient information into the patient's EMR by an authorized individual presented an obstacle that caused some offices to abandon the use of EMRs completely. For example, the person manually submitting the information often could not submit the information quickly enough for use by the attending physician during the physician's visit with the patient, requiring the physician to wait for the information to become available via the EMR system. Furthermore, manual submission of the information was susceptible to human error, and cost the caregiver the labor involved.

8. As of approximately March 2001, laws such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulated a caregiver's use of EMRs so as to ensure a patient's privacy. These laws required caregivers to prevent unauthorized individuals, including individuals outside their organization, from having access to the EMRs. As a result, even when implementing an EMR software system on-site, I was not allowed to view any EMRs relating to actual patients.

9. In order to comply with the privacy laws of HIPAA, it is very important to maintain confidentiality of a patient's identity and information. To maintain the confidentiality of the patient, only authorized persons can input the information into the EMR. Therefore, medical practices would input the information by having the patient fill out a form with the information and then having an authorized person manually enter the information, having a patient sit with an authorized person and provide the information while the authorized person inputs the information into an EMR, or having the doctor or

nurse obtain the information directly from the patient during the patient's visit, and then having the doctor or nurse input the information into the patient's EMR.

10. Thus, inputting of patient information into an EMR has always been a necessary but problematic obstacle to use of EMRs and has existed from at least as early as 1990. Although EMRs provide the ability to maintain patient information in an electronic format, the input of patient information into the EMR was, as of March 2001, performed manually, absent the PatientLink™ software developed by Ms. Whitson.

11. I recognized a need, at least as early as 1990, for a more efficient manner of inputting information received from a patient to the patient's EMR. I addressed the problem by educating system users of the demands of manual submission. The laws regulating the use of EMRs described above limit the manner in which this need may be addressed because only authorized individuals can be given full access to the EMR databases.

12. It is my understanding that the application is directed towards a process of allowing a patient to have limited input access to their EMR. It is my understanding that the method described in the application includes providing the patient with a machine readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient, and interfacing the card with a scanning type machine to convert the patient's written answers to a data stream. This data stream is then arranged into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific EMR, and the formatted data is sent to an assigned location for

importing into the patient's patient-specific EMR, wherein the patient's EMR contains patient-specific, clinical information regarding the patient's health.

13. I became aware of PatientLink™ in approximately 2000. I investigated and learned more about PatientLink™ during 2000, and it is my understanding from my investigations that PatientLink™ performs the method described in the independent claims. In particular, it is my understanding that PatientLink™ allows for importation of the patient information from the scan card by formatting the patient information into the form of a Health Level Seven ("HL7") laboratory record. HL7 is a recognized, standard protocol for coding laboratory information.

14. Although I was aware of EMRs and the HL7 protocol as of approximately March 2001, I was not aware that information recorded by a patient on a machine-readable card could be scanned by a machine and arranged into a data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record. Furthermore, I was unaware that a patient's medical history, environment, or symptoms could be formatted in the form of an HL7 laboratory record, or imported into the patient's electronic medical record by way of an interface engine.

15. It is also my opinion that given that EMRs and the HL7 protocol were well-known in the medical software industry, anyone trying to best solve the problem of inputting patient information into an EMR would have necessarily known of EMRs and the HL7 protocol. It is my opinion that noone ever thought to use the HL7 protocol to format the patient information for inputting into an EMR, other than Ms. Whitson, because the protocol had always only been used for laboratory information and because the industry was so

focused on making it easier for an authorized person, such as a doctor or nurse, to enter the information. Additionally, the patient information entered into an EMR is very different than laboratory information because it includes much more information, such as current symptoms, past medical history, family history, etc. In contrast, laboratory information only includes the result from a laboratory test, and therefore, the HL7 protocol is limited in the types of information, i.e., lab results, that it will accept.

16. As of approximately March 2001, I was not aware of a method for inputting information obtained from a patient into the patient's EMR, other than manual submission, described above in Paragraph 9. To my knowledge, the problems relating to the manual input of patient information into an EMR persist today, absent the invention described in the independent claims of the Application and sold as the PatientLink™ software. Furthermore, to my knowledge the invention described in the independent claims is to date the only method of automatically inputting patient information received from the patient into the patient's EMR. This is extremely beneficial because it allows automation of inputting the patient information so that an authorized person does not have to manually input the information. This results in better care of the patient, because the doctor or nurse can focus on diagnosing and treating the patient rather than transcribing the patient information into an EMR. I am not aware of any product that performs all of the functions recited in the independent claims, other than the PatientLink™ software.

17. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Rhetah Kwan — Rhetah Kwan

7/8/08 — Date